I

104TH CONGRESS
2D SESSION

H. R. 4270

To require reporting on research and development expenditures for drugs approved for marketing, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 27, 1996

Mr. SANDERS introduced the following bill; which was referred to the Committee on Commerce

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A BILL

To require reporting on research and development expenditures for drugs approved for marketing, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Health Care Research and Development and Consumer Protection Act''.

SEC. 2. FINDINGS.

The Congress makes the following findings:

(1) Public health needs are advanced by the development and distribution of new drug therapies

(2) The public interest in the development of new drug therapies is parallel to the public interest in controlling public and private health care costs.

(3) The Federal Government needs mechanisms to ensure that portions of revenues from the sale of drugs to consumers are reinvested in the research and development of new technologies.

(4) The Federal Government is the single largest supporter of biomedical research in the world, spending $33 billion in 1994 alone for biomedical and related health research.

(5) The Federal Government provides 80 percent of the monies spent each year for fundamental biomedical research at universities, medical schools, and other non-profit institutions.

(6) Of all the cancer drugs developed since the founding of the National Cancer Institute's new drug program in 1955 and approved for marketing by the Food and Drug Administration through 1992, 34 of 37 cancer drugs, or 92 percent, were developed with taxpayer funds.

(7) The public should not have to pay twice for health care inventions, first as taxpayers and second as consumers.

(8) The Department of Health and Human Services has the responsibility for funding basic biomedical research, for funding medical treatment through the programs under titles XVIII and XIX of the Social Security Act, for providing direct medical care, and, more generally, for protecting the health and safety of the public, it is incumbent upon the Secretary of Health and Human Services to require a reasonable relationship between the pricing of drugs, the public investment in those drugs, and the health and safety needs of the public.

(9) The Department of Health and Human Services, academic researchers, and the general public have the right to know, but lack the necessary information about, information about the actual costs for drug development, the general revenues generated from the sale of pharmaceutical drugs, and the taxpayer's investment in new drug development.

(10) The Department of Health and Human Services lacks the necessary information to make appropriate decisions about the reasonableness of drug prices or the impact of its policies on research and development of new medical technologies.

SEC. 3. REPORT ON RESEARCH OF THE FEDERAL GOVERNMENT.

(a) INVOLVEMENT OF THE FEDERAL GOVERNMENT.—For each drug for which an application under section 505, 507, or 512 of the Federal Food, Drug, and Cosmetic Act has been approved the following shall be reported to the Secretary of Health and Human Services:

(1) Each patent, cooperative research and development agreement under section 12 of the Stevenson-Wydler Technology Innovation Act of 1980, or other contractual agreement with the Federal Government which contributed to the development of the drug. The dollar amount of Federal funds expended, the agency of the Federal Government which provided such funds, the dates of any contractual agreements, and the nature of the research and development activity shall be included in the report.

(2) Each grant, contract, or other funding mechanism of the Federal Government which was used to support research or development activities with respect to the drug, including any grant or contract by the Federal Government to an institution of higher education or other non profit institution or other funds expended by the Federal Government on research and development which directly contributed to the development of the drug. The dollar amount

of Federal funds expended, the agency of the Federal Government which provided such funds, the dates of any contractual agreements, and the nature of the research and development activity shall be included in the report.

The Secretary shall make such report available to the public.

(b) RESEARCH AND DEVELOPMENT.—

(1) IN GENERAL.—For each drug for which an application under section 505, 507, or 512 of the Federal Food, Drug, and Cosmetic Act has been approved the total amount expended for each type of research and development of the drug in each calendar year, including pre-clinical research and phase I, II, and III clinical trials, the entity which made the expenditures, and the amount provided by the Federal Government shall be reported to the Secretary of Health and Human Services.

(2) PUBLIC DISCLOSURE OF DATA.—If a drug is protected under section 527(a) of the Federal Food, Drug, and Cosmetic Act or under a patent, the material reported under paragraph (1) for such drug shall be made available by the Secretary to the public. If a drug is not protected under such section or a patent, the Secretary shall make the report

available to the public in a form which does not identify individual entities.

SEC. 4. REASONABLE PRICE AGREEMENT.

(a) IN GENERAL.—If any Federal agency or any nonprofit entity undertakes federally funded health care research and development and is to convey or provide a patent or other exclusive right to use such research and development for a drug or other health care technology, such agency or entity shall not make such conveyance or provide such patent or other right until the person who will receive such patent or other right first agrees to a reasonable pricing agreement with the Secretary of Health and Human Services or the Secretary makes a determination that the public interest is served by a waiver of the reasonable pricing agreement provided in accordance with subsection (b).

(b) WAIVER.—No waiver shall take effect under subsection (a) before the public is given notice of the proposed waiver and provided a reasonable opportunity to comment on the proposed waiver. A decision to grant a waiver shall set out the Secretary's finding that such a waiver is in the public interest.

SEC. 5. PURCHASE OF DRUGS DEVELOPED WITH TAXPAYER SUPPORT.

For any drug approved for marketing by the Food and Drug Administration which was developed with significant Federal support, the Secretary of Health and Human Services shall review the price of the drug for purposes of determining a reasonable price for Federal reimbursements under the programs under titles XVIII and XIX of the Social Security Act and other Federal programs that elect to participate in the Secretary's reasonable pricing program, In determining a reasonable price for a drug, the Secretary shall consider—

(1) the public interest in continued health care research and development,

(2) the contribution of the person marketing such drug to the drug research and development expenses, including the amount, timing, and risk of investment in such research and development,

(3) the contribution of the Federal Government to the research and development of such drug, including the amount, timing, and risk of investment in such research and development,

(4) the therapeutic value of such drug,

(5) the number of patients who are expected to purchase such drug,

(6) the cost of producing and marketing of such drug,

(7) the cost of therapies which are similar to the therapy using such drug, and

(8) other relevant factors.

SEC. 6. MATERIAL TRANSFER AGREEMENT.

If in connection with research and development for health care technologies, the Secretary of Health and Human Services determines that the public interest will be advanced by the ability of the Secretary to conduct research on biological substances or other materials, the Secretary shall have the authority to compel the owner of such substances or materials to provide the Secretary with such substances or materials in accordance with a materials transfer agreement. The agreement shall—

(1) provide the owner of such substances or materials compensation for the costs incurred in making the transfer to the Secretary;

(2) define the terms and conditions under which the Secretary may use the materials;

(3) not grant rights in intellectual property or rights for commercial purposes; and

(4) require that the material be used for research purposes only.

SEC. 7. PROMOTION OF RESEARCH AND DEVELOPMENT.

(a) ACCOUNT.—Any person engaged in the manufacture of drugs for introduction into interstate commerce shall, in accordance with subsection (b), establish for each drug an account for funds to be reinvested in research and development for health care technologies.

(b) REINVESTMENT IN RESEARCH AND DEVELOPMENT.—To insure that adequate funds are being made available for research and development of new health care technologies, the Secretary of Health and Human Services shall establish for persons engaged in the manufacture of drugs for introduction into interstate commerce the minimum amount such person should make available for research and development of its new health care technologies based upon a percentage of sales revenue for that drug. The Secretary may require different percentages for minimum reinvestment for different classes of drugs based upon patient protection, orphan drug status, or magnitude of sales.

(c) ADDITIONAL RULES.—The Secretary shall adopt regulations concerning qualifying research and development expenditures and the reporting requirements for persons who are subject to subsections (a) and (b).

SEC. 8. REPORTS ON SALES.

Any person engaged in the manufacture and sale of drugs approved under section 505, 507, or 512 of the Fed-

eral Food, Drug, and Cosmetic Act shall report to the Health Care Financing Administration the total number of each drug it has sold and the total revenue it has received from such sales, including sales made outside the United States.

SEC. 9. GOVERNMENT EXPENDITURE ON PRESCRIPTION DRUGS.

The Secretary of Health and Human Services shall report to the Congress annually on the estimate of the amount of money the Federal government expends, directly or through reimbursement, for the purchase of prescription drugs, including an estimate of the amount of money expended each year on drugs which were developed with significant Federal support.

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